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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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Implants for sports medicine - Interference screw

运动医学植入器械 肌腱韧带固定螺钉

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1. Structure and drafting rules for standardization documents" Drafting. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Technical Committee for Standardization of Surgical Implants and Orthopedic Devices (SAC/TC110). This document was drafted by: Dabao Medical Technology Co., Ltd., Tianjin Medical Device Quality Supervision and Inspection Center, National Drug Administration Medical Device Technical Review Center of the State Food and Drug Administration, Greater Bay Area Center for Medical Device Technical Review and Inspection of the State Food and Drug Administration, Guangdong Medical Medical Device Quality Supervision and Inspection Institute, Beijing Deyi Damei Medical Technology Co., Ltd., Beijing Tianxing Bomaidi Medical Device Co., Ltd., Yunyi (Beijing) Medical Devices Co., Ltd., Beijing Fule Technology Development Co., Ltd., Beijing Natong Technology Group Co., Ltd., Smith & Nephew Medical Products Products International Trading (Shanghai) Co., Ltd., Stryker (Beijing) Medical Devices Co., Ltd. The main drafters of this document are: Zeng Da, Ye Yanjie, Zhao Binghui, Yao Li, Min Yue, Li Xiaoyun, Han Dan, Yuan Sheng, Xie Shengfen, Chen Xiaojun, Kong Qingjun, Wei Ning, Hou Suhua, Dong Wenxing, Liu Jimei, Zhao Xuedong, Miao Guoshuai, Zhao Wenwen, He Xueqin, Zhang Haiming. Sports Medicine Implants Tendon Ligament Fixation Screws

1 Scope

YY/T 1922 is the product standard for the interference screw, the implant that wedges a tendon graft into a bone tunnel during cruciate ligament reconstruction. It is part of the Chinese sports medicine implant series, alongside YY/T 1988 on meniscus repair systems and YY/T 0965 on artificial ligaments. Fixation strength at time zero is what the device is bought for, because the graft is at its weakest before biological healing takes over, and the screw's thread form, insertion torque and material, which may be metal, polymer or a resorbable composite, determine both the initial hold and what remains in the bone years later. For a manufacturer or an importer of interference screws seeking Chinese registration, this is the standard the product specification and testing follow.

This document specifies the performance requirements for tendon and ligament fixation screws for sports medicine implants, describes the corresponding test methods, and specifies the content of manufacture, sterilization, biological safety evaluation, packaging and information provided by the manufacturer. This document applies to sports medicine implants tendon ligament fixation screws (hereinafter referred to as "tendon ligament fixation screws"), which are available for Tendon-ligament grafts are fixed in bone tunnels for use in sports medicine surgery.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 10610 Geometric Product Specification (GPS) Rules and methods for evaluating surface structure by surface structure profile method

GB/T 14233.1 Inspection methods for medical infusion, blood transfusion and injection equipment Part

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Tendon ligament interference screw A medical device for fixing soft tissue grafts or bone-tendon-bone grafts by compression, which may consist of a screw or a screw and a sheath.

3.2 Insertion force The maximum pressure required to fully insert a knock-in sheath into a test block. Note

1.Applicable to tendon and ligament fixation screws consisting of a screw and a sheath.

Note

2.The unit is Newton (N).

3.3 Fixation strength After fixing the tendon-ligament fixing screw and the ligament simulation (or bone-tendon-bone simulation) on the test block, The maximum force required to pull a tendon-bone mimic out of a test block.

Note. The unit is Newton (N).